

**Remarks**

Claims 37-62 are pending. Claims 48-50 and 53 have been withdrawn. Claims 1-36 have been cancelled. Claim 51 has been amended. No new matter has been added.

**Claim Objection**

Claim 51 is objected to for being dependent on withdrawn claim 50. Applicants have amended the claim to correct this.

In view of the foregoing, Applicants respectfully request withdrawal of the objection.

**Rejections Under 35 U.S.C. §112**

Claims 37-47, 51-52 and 54-62 are rejected under 35 U.S.C. §112, first paragraph for allegedly failing to comply with the written description requirement. Applicants respectfully disagree.

The Examiner contends that the specification provides written description for only for the 5 modified HA peptides conjugated to OMPC that are shown in the Examples of the specification. Applicants believe that the specification provides adequate teaching for one skilled in the art to use the claimed methods. The claimed methods specify that peptide load and/or solubility are increased because of the peptide modification.

The Examiner contends that the biomolecules made by the claimed methods are not adequately described because they are not described in a precise enough fashion (such as by structure, formula or chemical name) and only recite a functional characteristic. The Examiner states that the written description requirement is not met by merely stating a functional

characteristic and providing a method of obtaining the claimed characteristic without a correlation between function and structure of the sequence. However, Applicants contend that there is a nexus between the recited functional characteristic and the sequence of the peptides in the claimed methods.

The functional characteristic of having increased peptide load is dependant on the peptide's alteration of a lowered isoelectric point. This is not merely a functional description but rather an alteration with a specific outcome that can be tested by one skilled in the art using routine techniques. The specification describes a number of ways in which a peptide's isoelectric point can be lowered and one skilled in the art would use methods appropriate for their peptide of choice. Just because a particular sequence with a particular structural modification is not universally specified by the claims, this does not preclude having written description.

The written description requirement is applied in the context of the particular invention and the state of the knowledge. Capon v. Eshhar, 418 F.3d 1349, 1357, 76 USPQ2d 1078, 1084 (Fed. Cir. 2005). In order to provide an adequate written description, the specification must reasonably convey to the artisan that the inventor had possession at that time of the claimed subject matter. While a patent applicant does not have to describe exactly the subject matter claimed, the description must clearly allow persons of ordinary skill in the art to recognize that the applicant invented what is claimed. Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1563, 19 U.S.P.Q.2d 1111, 1116 (Fed. Cir. 1991) (citing In re Gosteli, 872 F.2d 1008, 1012, 10 U.S.P.Q.2d 1614, 1618 (Fed. Cir. 1989)). "The written description must communicate that which is needed to enable the skilled artisan to make and use the claimed invention." Kennecott Corp. v. Kyocera Int'l, Inc., 835 F.2d 1419, 1421, 5 U.S.P.Q.2d 1194, 1197 (Fed. Cir.

1987), cert. denied, 486 U.S. 1008 (1988). In the present situation, the subject matter of the claims is described and enabled by the specification within the meaning of 35 U.S.C. § 112 first paragraph.

The Examiner is concerned by the fact that the broadest claims encompass conjugation of any peptide (not restricted to sequence) and any carrier. However, Applicants point out that the isoelectric point of any peptide can be lowered, regardless of its initial sequence. The lowering of the isoelectric point is what allows the peptide to have increased load onto a carrier. Applicants have disclosed this connection of structure and function. The Examiner has not provided any evidence of a peptide/carrier that does not work in the methods of the invention.

In view of the foregoing, Applicants respectfully request withdrawal of the rejections under §112.

### **Conclusion**

It is believed that the claims now pending are in condition for allowance. Early and favorable action by the Examiner is earnestly requested.

**Authorization**

The Commissioner is hereby authorized to charge to deposit account 13-2755 \$130.00 to pay the fee under 37 C.F.R. §1.136(a) for an Extension of Time for one month and \$810.00 to pay the fee under 37 C.F.R. §1.114 for a Request for Continued Examination. Additionally, the Commissioner is hereby authorized to charge any additional fees which may be required for consideration of this Amendment to deposit account 13-2755.

Respectfully submitted,

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